510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY TEMPLATE

A. 510(k) Number:

K050278

B. Purpose for Submission:

To clarify indications for use and introduce additional performance data in the labeling (package insert).

C. Measurand:

D-dimer

D. Type of Test:

Quantitative, Turbidimetric Immunoassay

E. Applicant:

Instrumentation Laboratory Company

F. Proprietary and Established Names:

HemosIL D-Dimer

G. Regulatory Information:

1. Regulation section:

   864.7320, Fibrinogen/fibrin degradation product assay

2. Classification:

   Class II

3. Product code:

   DAP, Fibrinogen and Fibrin Split Products, Antigen, Antiserum, Control

4. Panel:

Hematology (81)

H. Intended Use:

1. Intended use(s):

   HemosIL D-Dimer is an automated latex enhanced immunoassay for the quantitative determination of D-Dimer in human citrated plasma on IL Coagulation Systems as an aid in the diagnosis of venous thromboembolism (VTE) [deep venous thrombosis (DVT) and pulmonary embolism (PE)].

2. Indication(s) for use:

   HemosIL D-Dimer is an automated latex enhanced immunoassay for the quantitative determination of D-Dimer in human citrated plasma on IL Coagulation Systems as an aid in the diagnosis of venous thromboembolism (VTE) [deep venous thrombosis (DVT) and pulmonary embolism (PE)].

3. Special conditions for use statement(s):

   Not applicable.

4. Special instrument requirements:

   Not applicable.

I. Device Description:

The HemosIL D-Dimer Kit consists of: Latex Reagent, 4 vials x 3 mL of a lyophilized suspension of polystyrene latex particles coated with a mouse monoclonal antibody (MA-8D3) directed against D-Dimer containing bovine serum albumin, buffer, stabilizers and preservative; Reaction Buffer, 3 vials x 9 mL of phosphate buffer containing bovine serum albumin, stabilizers and preservative; D-Dimer Calibrator, 2 vials x 1 mL of a lyophilized solution of D-Dimer partially purified from human fibrin digested with human plasmin containing bovine serum albumin, buffer, stabilizers and preservative.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   HemosIL D-Dimer

2. Predicate 510(k) number(s):

   K972696

3. Comparison with predicate:

Similarities		
Item	Device	Predicate
	HemosIL D-Dimer	***HemosIL D-Dimer***
Name	Same	Same
Intended Use	Used for quantitative determination of D-Dimer in human plasma on IL Coagulation Systems.	Same with the addition of …as an aid in the diagnosis of venous thromboembolism (VTE) [deep venous thrombosis (DVT) and pulmonary embolism (PE)].
Methodology	Latex Agglutination	Same
Sample Type	Citrated Plasma Only	Same

Differences		
Item	Device	Predicate
Package insert: Expected values, **ACL TOP System** results.	Number of donor samples tested = 231, Upper Normal Range = 232 ng/ml	Number of donor samples tested = 123, Upper Normal Range = 316 ng/ml

K. Standard/Guidance Document Referenced (if applicable):

Not applicable.

L. Test Principle:

The HemosIL D-Dimer Latex Reagent is a suspension of latex particles coated with a monoclonal antibody specific for the D-Dimer domain included in fibrin soluble derivatives. When plasma containing D-Dimer is mixed with the D-Dimer Latex Reagent and Reaction Buffer, the coated latex particles agglutinate. The degree of agglutination is directly proportional to the concentration of D-Dimer in the sample and is determined by measuring the decrease of the transmitted light caused by the aggregates (turbidimetric immunoassay).

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. *Precision/Reproducibility:*

Not applicable for purpose of this submission. See data provided in previously 510(k) cleared predicate (K972696).

b. *Linearity/assay reportable range:*

Not applicable for purpose of this submission. See data provided in previously 510(k) cleared predicate (K972696).

c. *Traceability, Stability, Expected values (controls, calibrators, or methods):*

Not applicable for purpose of this submission. See data provided in previously 510(k) cleared predicate (K972696).

d. *Detection limit:*

Not applicable for purpose of this submission. See data provided in previously 510(k) cleared predicate (K972696).

e. *Analytical specificity:*

Not applicable for purpose of this submission. See data provided in previously 510(k) cleared predicate (K972696).

f. *Assay cut-off:*

Not applicable for purpose of this submission. See data provided in previously 510(k) cleared predicate (K972696).

2. Comparison studies:

a. *Method comparison with predicate device:*

Not applicable for purpose of this submission. See data provided in previously 510(k) cleared predicate (K972696).

b. *Matrix comparison:*

Not applicable.

3. Clinical studies:

a. *Clinical Sensitivity:*

An outcome study was performed on 300 frozen samples from patients

admitted consecutively to an emergency unit with suspected PE or DVT (frequency of venous thromboembolic disease : 26%). Of the 300 samples, 78 were confirmed as VTE positive (47 PE and 31 DVT) by standard objective tests and the remaining 222 were confirmed as negative. Samples with insrument error results were not included in calculations.

The result are as follows (based on a cut-off of 230 ng/mL) :

Instrument System	N	Sensitivity (96% CI)	Specificity (95% CI)	Negative Predicitive Value
ACL 8000/9000/10000	297	100% (95.2%-100%)	38% (31.4%-44.6%)	100% (95.7%-100%)
ACL TOP	294	100% (95.1%-100%)	36% (29.6%-42.6%)	100% (95.4%-100%)

*b. Clinical specificity**:***

Refer to table above (3.*a*.).

c. Other clinical supportive data (when a. and b. are not applicable):

4. Clinical cut-off**:**

Not applicable.

5. Expected values/Reference range:

Refer to predicate (K972696) for normal range results for the ACL Family, and ACL Futura/ ACL Advance Systems.

Data was provided for a comprehensive normal range study on the ACL TOP System and the resultant data was used to update the product insert. However, the insert states that each laboratory should establish its own normal range.

The results of the normal range study are as follows:

	95% Limit	90%CI
Lower	61.4	53.3 to 69.4
Upper	231.9	223.8 to 239.9

N. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

O. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.